UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,376	07/01/2005	Susan L. Kalled	08201.0028-00000	2363

65779 7590 01/23/2009

BIOGEN IDEC / FINNEGAN HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,376	KALLED ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignments (3 pages total)*.

DETAILED ACTION

1. The remarks and amendments filed 19 December 2008 have been entered. Claims 1 – 20 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group III in the reply filed on 19 December 2008 is acknowledged. The traversal is on the ground(s) that Groups 1, 3, and 4 share the same technical feature and therefore should be rejoined. This is found persuasive in part and not persuasive in part for the following reasons.

Applicant argues that the claims of Groups 1 and 3 are now drawn to administering soluble BCMA polypeptides, or antibodies that bind to BCMA for treating disease and therefore the claims should be rejoined and examiner, as they share the same technical feature, namely administering a protein product that inhibits binding of BAFF (the BCMA ligand) to BCMA. This reasoning is persuasive, Groups 1 and 3 are hereby rejoined, and the restriction requirement between these two groups is vacated.

However, the argument that group 4 (claim 16) has the same technical feature is not persuasive. Claim 16 requires many technical features which are not present in claims 1 – 15 and 17 - 20. The claim requires two binding mixtures and requires multiple steps of measuring binding, none of which is required for the methods of original groups 1 and 3. Additionally claim 16 is a screening method, whereas the other claims are drawn to treatment or delaying of disease. Therefore the restriction between group 4 and all other groups is maintained.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 19 December 2008.

4. Claims 1 – 15 and 17 – 20 are under examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially identical" in claim 9 is a relative term which renders the claim indefinite. The term "substantially identical" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A skilled artisan could not tell whether or not any given protein sequence is "substantially identical" to the recited sequence, since what is "substantially identical" for one person is not necessarily "substantially identical" for another. Would a sequence 90% identical be "substantially identical"? What if the sequence were only 50% identical? Or 20% identical?

Claim 13 is confusing and indefinite because it recites the phrase "defined conditions", but the conditions are not defined. A skilled artisan could not determine what conditions are encompassed by this language.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 6, 8 – 11, 13 – 15, and 17 – 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Gross (U.S. Patent Application Publication 2006/0286093, published 21 December 2006, filed 20 July 2006, claiming benefit of an earlier-filed application with the same disclosure filed 27 July 2000, as well as other applications filed 7 January 1999 - 11 May 2000).

Gross teaches that BCMA has the sequence of SEQ ID NO:8; see paragraph [0041] on p. 3. Thus further references by Gross to SEQ ID NO:8 are to the protein known in the art as BCMA.

Gross teaches and claims methods of treating disease by administering certain polypeptide fragments of BCMA. See for example claims 3 – 4, which encompass treatment of

multiple sclerosis by administering soluble (i.e., extracellular) BCMA. SEQ ID NO:8 from Gross is identical to SEQ ID NO:1 from the present application, the latter is disclosed as being human BCMA (specification, paragraph [0025]). See attached sequence alignment. The specification discloses that the extracellular ligand-binding portion of BCMA is about residue 1 to about residue 50 (paragraph [0051]). As Gross claims treating multiple sclerosis by administering residues 1 - 48 of BCMA (see claim 1, part (b), as well as claims 3 - 4), the reference anticipates present claims 1 - 2. Claims 3 - 5 are anticipated as they recite certain effects which will happen upon administration of the soluble polypeptide. Additionally, note that Gross teaches and claims treating the same diseases by administering antibodies that bind to BCMA; see for example claims 2 and 9 – 10. Claim 6 is anticipated as Gross also teaches treating insulin dependent diabetes; see for example claim 4 of Gross. Claim 8 is anticipated as the polypeptide recited in claim 1 part (b) from Gross is the ligand-binding domain (see present specification, paragraph [0051]). Claim 9 is anticipated as Gross's polypeptide, particularly those recited in claim 1 part (b) and claim 1 part (g) not only comprise sequences "substantially identical" to the recited sequences, the latter comprises a sequence identical to the recited residues. Note claims 3 – 4 from Gross indicate that these polypeptides are to be administered to mammals for treating multiple sclerosis. Claim 10 is anticipated as the polypeptides recited in claim 1 part (b) and claim 1 part (g) comprise residues 8 – 41 of SEQ ID NO:1. Claim 11 is anticipated as the polypeptide recited by Gross in claim 1 part (g) comprises residues 1-51. Claim 13 is anticipated as the polypeptides that Gross teaches should be administered include multiple portions of the amino acid sequence of SEQ ID NO:8 (which is identical to present SEQ ID NO:1), and the reference indicates that SEQ ID NO:8 is BCMA (paragraph [0041]) and that BCMA binds BAFF (paragraph [0004]). Claim 14 is anticipated as the nucleic acid encoding the protein that is Gross's SEQ ID NO:8 will inherently bind under the recited conditions. Claim 15 is anticipated as Gross teaches that one embodiment of the invention is using the soluble BCMA polypeptides described in the reference fused to the Fc region of an immunoglobulin (see for example paragraph [0134]). Claims 17 – 18 are anticipated for the same reasons as claims 1 - 2; they require only the step of administering the soluble polypeptide to patients with multiple sclerosis.

The reference by Gross is a U.S. Patent Application Publication claiming the same patentable invention, and therefore it cannot be overcome by a declaration filed under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 –15 and 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (U.S. Patent Application Publication 2006/0286093) in view of Biogen (WO 01/12812).

The reasons why claims 1 – 6, 8 – 11, 13 – 15, and 17 – 18 are anticipated by Gross are discussed in the rejection under 35 USC 102 above. Gross teaches and claims treatment of diseases, including multiple sclerosis, by administering either soluble BCMA or antibodies that bind to BCMA, and Gross explicitly teaches treating primates (see for example claims 16, 27, and 33), which is on point to claim 7, as well as treating diseases by administering fusion proteins between soluble BCMA and Fc (see for example paragraph [0134]), which is relevant to claim 20. Gross also teaches that the methods are suitable for treating many other diseases, including autoimmune diseases generally, renal disease, and rheumatoid arthritis. However Gross does not explicitly teach treating humans as recited in present claim 7 and does not explicitly teach administering soluble BCMA comprising residues 24 - 74 of SEQ ID NO:3 as recited in claim 19, or full-length SEQ ID NO:3 as recited in claim 12.

Biogen teaches administering BAFF-R, also known as BCMA, for treatment of many diseases including autoimmunue diseases generally, renal diseases, and other B-cell-associated disorders. See for example p. 3 lines 16 – 33. Biogen teaches that the BCMA

polypeptide can be fused to the Fc region of an immunoglobulin, which is on point to claims 19 – 20 (see p. 4 lines 3 – 12). Biogen teaches soluble BCMA, which is on point to all claims under examination, and specifically points the artisan of ordinary skill to select residues 8 - 41 as recited in claim 10, or residues 1 - 51 as recited in claim 10, for use in the treatment of disease (see p. 11 line 32 - p. 12 line 18), as well as antibodies against BCMA (see p. 12 line 20 - p. 14 line 17). Biogen teaches SEQ ID NO:3, which is identical to applicant's SEQ ID NO:3 and therefore on point to present claims 12 and 19 – 20, is a preferred form of the BCMA to be used in the disclosed methods (see enclosed alignment for evidence of sequence identity; see also Biogen p. 5 lines 8 – 12, as well as Figure 2). Biogen explicitly teaches that the methods should be used to treat humans, which is on point to present claim 7 (see p. 9 lines 29 – 31). However while Biogen teaches that the BCMA molecules can be used to treat autoimmune diseases is general, the reference does not explicitly teach treatment of multiple sclerosis as recited in claims 12, 17 – 18 and encompassed by claims 19 - 20.

It would have been obvious to one of ordinary skill in the art to modify the teachings of Gross, who teaches treatment of multiple sclerosis by administering BCMA polypeptides, by using the protein of SEQ ID NO:3 as taught by Biogen, thereby arriving at the invention of claims 12 and 19 – 20. As both Gross and Biogen teach that autoimmune diseases can be treated by administering BCMA polypeptides including BCMA-Fc fusion proteins, and Gross specifically points to multiple sclerosis as a disease that can be treated, it would have been reasonable to expect success in treating this disease by administering the protein taught by Biogen. It is prima facie obvious to substitute equivalents known to be effective for the same purpose (MPEP § 2144.06(II); in this case both Gross and Biogen teach the efficacy of treating autoimmune diseases by administering BCMA-Fc fusions. Additionally it would have been obvious to one of ordinary skill in the art to treat humans, specifically disclosed by Biogen, as the artisan of ordinary skill would have been motivated to treat human patients.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting

rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60 – 85 of copending Application No. 11/065669. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating disease by administering anti-BCMA antibodies. Note Sjogren's syndrome, recited in claim 60 of the '669 application, is a specific form of neurodegenerative immunological disorder.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 7, 13 – 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60– 69, 72, and 74 – 78 of copending Application No. 12/061398.

Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass treating disease by administering anti-BCMA antibodies or soluble BCMA polypeptides. Note Sjogren's syndrome, recited in claim 60 of the '398 application, is a specific form of neurodegenerative immunological disorder. This is

a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
January 21, 2009